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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/051,670	09/08/98	NAKAGAWA	FJN-063

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PATENT ADMINISTRATOR  
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EXAMINER
ROMEO, D.

ART UNIT	PAPER NUMBER
1646	10

DATE MAILED: 06/23/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.  
09/051,670

Applicant(s)  
Nakagawa et al.

Examiner  
David S. Romeo

Group Art Unit  
1646



☒ Responsive to communication(s) filed on 3-8-99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1, 2, 5, and 6 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 2, 5, and 6 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

1. The amendment filed 03/08/99 (Paper No. 7) has been entered in full. Claims 1, 2, 5 and 6 are pending and are being examined.

#### *Claim Objections*

5 2. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 is limited to a Markush group consisting of genera of nucleic acid molecules, *i.e.* exons of an OCIF gene. The subject matter of parent claim 1 is  
10 limited to a Markush group consisting of species of nucleic acid molecules. The genera do not further limit the species.

#### *Claim Rejections - 35 USC § 101*

3. 35 U.S.C. 101 reads as follows:

15       Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1, 2 and 5 are rejected under 35 U.S.C. 101 because

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the claimed invention is directed to non-statutory subject matter. The claimed DNA and protein read on a product as it occurs in nature. Also, a "DNA sequence" is a description of the linear order bases in a DNA molecule; it is not an article of manufacture. It is suggested that the claims recite "[A]n isolated DNA molecule comprising a nucleotide sequence" and "[A]n isolated protein".

***Claim Rejections - 35 USC § 112***

5. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

10 Claim 6 recites a method of producing a protein comprising the amino acid sequence of SEQ ID NO:3, using either SEQ ID NO:1 or SEQ ID NO:2. However, neither SEQ ID NO:1 nor SEQ ID NO:2 encode the complete amino acid sequence of SEQ ID NO:3. The specification has not told the skilled artisan how to make a protein using a DNA molecule that does not encode the complete amino acid sequence of that protein.

15 6. Claims 2, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 2 is indefinite because it limits a DNA species, *e.g.* SEQ ID NO:1, to a DNA comprising a genus of DNA molecules. The metes and bounds of the claim are not discernible or clearly set forth.

5        Claim 2 is indefinite because it recites the term "OCIF gene". Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "OCIF gene" an artisan cannot determine what additional or material functional limitations are placed upon a claim by the presence of this element.

Claim 5 is indefinite because the molecular weight of a protein varies with the method of determination. The metes and bounds of the claim(s) are not clearly set forth.

10        Claim 6 is indefinite because it recites the term "express vector". Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "express vector" an artisan cannot determine what additional or material functional limitations are placed upon a claim by the presence of this element. It is suggested that "expression vector" be used instead.

15        Claim 6 recites the limitation "the expression vector" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

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§ 2172.01. The claim omits steps indicating how the expression is induced. It is suggested that the claim include transforming a host cell with the expression vector and culturing said host cell.

Claim 6 is indefinite because it lacks a process step which clearly relates back to the claim preamble and it is unclear what process is to be achieved; an intended use is not the same as achieving a result; it is unclear what result of the process can be inferred. It is suggested that the claim recite "whereby said protein is produced and isolated from said culture", or something similar, assuming the suggestions in the preceding paragraph are adopted.

### ***Conclusion***

7. SEQ ID NOs:1, 2 and 3 are free of the prior art of record.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Romeo whose telephone number is (703) 305-4050. The examiner can normally be reached on Monday through Friday from 6:45 a.m. to 3:15 p.m.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242.

Faxed draft or informal communications should be directed to the examiner at (703) 308-0294.

10 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
DAVID ROMEO  
PATENT EXAMINER

June 19, 1999